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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Appl. No.	:	10/650,603	Confirmation No. 8329
Applicant	:	David H. Burkett	
Filed	:	August 28, 2003	
Art Unit	:	3726	
Examiner	:	John C. Hong	
Title	:	WIRE JOINT AND METHOD	
Docket No.:	:	ACS-65356 (G1747USD1)	
Customer No.	:	24201	June 13, 2008

APPEAL BRIEF

Mail Stop Appeal Brief - PATENTS
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

This Appeal Brief is being filed pursuant to the Notice of Appeal that was filed February 27, 2007 and in conjunction with a Request for Reconsideration of the March 17, 2008 Dismissal of the Petition to Revive that had been filed November 29, 2007. The requisite filing fee of $510 is being paid by credit card with this electronic transmission.

INTRODUCTION

The present invention generally relates to a guide wire and more specifically, to a guide wire that is formed of different materials along its length. In an effort to exploit the physical properties that different materials have to offer, lengths of small diameter wires have previously been joined end-to-end in the construction of a guide wire. The claimed invention provides a less expensive and less cumbersome method of forming such a joint as well as the guide wire that results therefrom.

The present application, U.S. Serial No. 10/650,603, was filed on August 28, 2003 and was finally rejected on November 27, 2006.

REQUEST FOR ORAL ARGUMENT

An oral argument is requested. A separate request is attached hereto.

I. REAL PARTY IN INTEREST

The real party in interest is the assignee ADVANCED CARDIOVASCULAR SYSTEMS, INC.

II. RELATED APPEALS AND INTERFERENCES

None.

III. STATUS OF CLAIMS

Claims 1-15, 18 and 19 are pending and have been rejected.

Claims 16 and 17 had previously been canceled.

The rejections of claims 1-15, 18 and 19 are being appealed.

IV. STATUS OF AMENDMENTS

Upon the reopening of prosecution pursuant to the consideration of a pre-appeal brief, all claims were finally rejected in a Final Office Action dated November 27, 2006 (a copy of which is attached hereto as Exhibit 3).

No further amendments were filed.

A timely Notice of Appeal was filed February 27, 2007.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The present invention provides for a simpler, less labor intensive and therefore less costly method of joining two elongated sections of a guide wire end-to-end (page 1, lines 16-19). More specifically, the method provides for the forming of a female end in one section of wire, a male end in the other section of wire and securing the male end within the female end. As a result, only two components need be formed, handled and joined (page 2, lines 6-12).

As is shown in Fig. 2 of the application (the drawings are attached hereto as Exhibit 2), the diameter of one wire 30 is reduced so as to define a male end 31 such that the first wire and male end comprise a first continuous material (page 5, lines 14-17). Fig. 2 additionally shows a second wire 25 having hole 28 formed so as to define a female end such that **the second wire and female end comprise a second continuous material** (page 5, lines 3-9). The male end is subsequently inserted into the female end and permanently secured therein by any of various processes (page 6, lines 6-8). The resulting structure is shown in Fig. 3, wherein the first and second wires are directly joined to one another without the need for the coupling sleeve of the prior art as depicted in Fig. 1. The guide wire has a smooth continuous outer surface and has but a single transition point 36 (page 6, lines 14-19).

The independent claims all unequivocally specify this feature (**in bold**):

1. A process for forming a guide wire for use in a medical procedure, comprising:

forming a male end at an extremity of a first elongated member formed of a first continuous material;

forming a female end at an extremity of a second elongated member, **the second elongated member and the female end being formed of a second continuous material**; and

permanently securing the male end of the first elongated member within the female end of the second elongated member.

9. A guide wire for use in a medical procedure, comprising:

a first elongated member having an extremity and a male end formed at the extremity, the first elongated member formed of a first continuous material;

a second elongated member including a second extremity, the second extremity of the second elongated member including a female end, **the second elongated member and the female end being formed of a second continuous material**;

wherein the male end is permanently secured within the female end of the second elongated member.

18. A guide wire, comprising:

an elongated proximal core portion having a female end disposed at the distal extremity, **the proximal core portion and female end formed from a first continuous material**;

a distal core portion having a male end disposed at the proximal extremity; and

a flexible body member;

wherein the male end is permanently secured within the female end and the flexible body member is disposed about and secured to the distal core portion.

19. A process for constructing a guidewire. comprising:

providing an elongated proximal core portion including a distal extremity and having a male end disposed at the distal extremity, the proximal core portion being formed from a first continuous material including stainless steel;

providing a distal core portion including a proximal extremity and having a female end with a predetermined depth disposed at the proximal extremity, **the distal core portion and female end being formed from a second continuous material** including a nickel-titanium alloy;

permanently securing the male end within the female end; and

disposing the flexible body member about the distal core portion.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

In the Final Office Action dated November 27, 2006, the Examiner had rejected:

Claims 1, 4-6, 9, 12, 13 and 18 under 35 U.S.C. §102(b) as being anticipated by Gambale et al. (U.S. Patent No. 5,031,636).

Claims 2, 3, 7, 8, 10, 11, 14 and 15 under 35 U.S.C. § 103(a) as obvious over Gambale et al. (U.S. Patent No. 5,031,636).

Claim 19 under 35 U.S.C. § 103(a) as being obvious over Gambale et al. (U.S. Patent No. 5,031,636) in view of Abrams et al. (U.S. Patent No. 5,341,818).

In view of the Examiner's rejections, Appellant respectfully submits that the grounds of rejection to be reviewed are as follows:

Ground 1: Whether independent claims 1, 9 and 18 as well as claims 4-6, 12 and 13 that depend therefrom are anticipated by Gambale et al.

Ground 2: Whether claims 2, 3, 7, 8, 10, 11, 14 and 15 are obvious in view of Gambale et al.

Ground 3: Whether claim 19 is obvious over Gambale et al. in view of Abrams et al.

VII. ARGUMENT

Ground 1:

The first issue on appeal is whether claims 1, 4-6, 9, 12, 13 and 18 are unpatentable under 35 U.S.C. § 102(b) as anticipated by Gambale et al. (U.S. Patent No. 5,031,636) (attached hereto as Exhibit 4). It is to be noted that the method and device shown and described in the cited reference are examples of precisely the type of prior art method and device that the present invention improves upon. As was set forth in the present application at page 1, lines 11-22, the conventional approach for joining two wires end-to-end involves a third element, i.e. a sleeve or tube. The end of one wire is crimped or otherwise fastened onto one end of the sleeve while the end of the second wire is crimped onto the other end of the sleeve. The present invention undertakes to form such joint **without** benefit of a third element. Consequently, each and every one of the rejected independent claims specifically call for, inter alia, one wire and its female end to be formed of a **continuous** material. This is a critical feature as it allows the joint to be formed without a third element. The Examiner's assertion that Gambale et al. teaches a female end formed of a continuous material is simply and patently not correct. Each and every example shown and described in the cited reference provides for one wire and its associated female end to be formed of **two** components – a necked down length of wire 28 and a "tube" 26 (FIGS. 2-4). As is set forth at column 6, lines 10-11, "The wall thickness of the tube should be selected so that it can be crimped easily..." Clearly, the tube comprises a distinct and separate component so consequently the female end of the device taught by the cited reference is most definitely not formed of a **continuous** material. Anticipation of independent claims 1, 9 and 18, and all of the claims that depend therefrom, is therefore undeniably avoided.

Furthermore, it should be noted that dependent claim 4 calls for the first elongated member and the second elongated member to be formed of different materials. Because the cited reference is directed to a joint that merely allows for a convenient way of increasing the length of a guide wire during a procedure, there is absolutely no suggestion that two different materials are to be used. Anticipation is therefore further avoided by claim 4.

Ground 2:

The second issue on appeal is whether claims 2, 3, 7, 8, 10, 11, 14 and 15 are unpatentable under 35 § U.S.C. § 103(a) as obvious over Gambale et al. Since all of these rejected claims depend from independent claims (claims 1 and 9) that call for one wire and the female end to be formed of a **continuous** material and the cited reference does not in any way suggest such a structure, let alone a method for forming such a structure, it is the applicant's position that obviousness is initially effectively avoided before the additional limitations of the individual dependent claims need even be considered. As was indicated above, the cited reference describes a conventional method for joining two sections of a guide wire to the extent that three components are used to form the joint – the two sections of wire and a joining sleeve or tube. The present invention provides a method and a guide wire that results therefrom in which only two components form the joint wherein one wire is directly joined to the other. This represents a substantial departure from the cited reference and no suggestion is made therein that anything other than a sleeve can successfully be used to form the joint, wherein the sleeve is described as preferably comprising a length of hypotube (column 6, lines 8-10) which is "readily available."

It must be noted that a guide wire for coronary applications has an extremely small outer diameter, as small as about 0.006" to 0.018" (specification page 7, line 10). What is unexpected is that such fine wires can be reliably **directly** joined to one another and be capable of transmitting the sufficient torque therethrough so as to maintain steerability (specification page 6, lines 12-14). Moreover, it is unexpected that a joint that requires the formation of an axial hole in such a fine wire can be manufactured in less time and at less cost than the conventional method that employs "readily available" hypotubing. It is therefore the applicant's position that all claims depending from independent claims 1 or 9 cannot reasonably be found to be obvious in view of the conventional joint and method as described in the cited reference.

Furthermore, in view of the fact that the cited reference teaches the use of "readily available hypotubing" to form the joint, its teaching cannot reasonably be characterized as rendering obvious the use of laser drilling or electrical discharge machining (claims 2, 3, 10 and 11) to form an axial cavity in the end of a fine wire. The cited reference is clearly not concerned with any reconfiguring of the wire that is to be joined to the male end of the joint, and to the extent that use of a "readily available" sleeve is taught, the reference actually teaches away from

the use of any of the claimed techniques for forming the female end of the joint. Obviousness is therefore further avoided by these four dependent claims.

Ground 3:

The third issue on appeal is whether claim 19 is unpatentable under 35 U.S.C. § 103(a) as obvious over Gambale et al. in view of Abrams et al. (U.S. Patent No. 5,341,818) (attached hereto as Exhibit 5). Notwithstanding the Examiner's characterization of the secondary reference as providing for the "distal core portion and female end being formed from a second **continuous** material", the reference in fact again teaches the use of a sleeve. This is clearly shown in FIG. 1 wherein the sleeve is identified by reference numeral 16, and is unequivocally described as such in the very passage cited by the Examiner (col 4, line 25-30): "... the guidewire .... has a solid core distal section ... and the connector is a hollow tubular shaped member which has an inner passageway adapted to receive the proximal end of the solid core distal section." The fact that the distal core and female end are NOT continuous could not be more clearly stated. In view of the fact that the secondary reference has precisely the same shortcomings as the primary reference as was argued above, obviousness is avoided for precisely the same reason.

CONCLUSION

For the foregoing reasons, it is submitted that the present invention as claimed is not anticipated by or obvious over the cited art and that the Examiner's rejections of claims 1-15, 18 and 19 were therefore erroneous. Appellant respectfully requests reversal of the rejection of claims 1-15, 18 and 19.

VIII. CLAIMS APPENDIX

PLEASE SEE EXHIBIT 1

IX. EVIDENCE EXHIBIT

EXHIBIT	DESCRIPTION
1.	Claims
2.	Drawings
3.	Final Office Action dated November 27, 2006
4.	U.S. Patent No. 5,031,636 to Gambale et al.
5.	U.S. Patent No. 5,341,818 to Abrams et al.

X. RELATED PROCEEDINGS EXHIBIT

NONE

In the event there are any further charges associated with the filing of the subject Appeal Brief, the Director of Patents and Trademarks is hereby authorized to charge our Deposit Account No. 06-2425.

Respectfully submitted,

FULWIDER PATTON LLP

/John S. Nagy/
John S. Nagy, Reg. No. 30,664

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EXHIBIT 1

U.S. Letters Patent Application No. 10/650,603
WIRE JOINT AND METHOD
Inventor: David H. Burkett; Filed: August 28, 2003
ACS Ref. No. 1747D; Fulwider Docket No. ACSG-65356

Pending Claims

1. (Previously presented): A process for forming a guide wire for use in a medical procedure, comprising:

forming a male end at an extremity of a first elongated member formed of a first continuous material;

forming a female end at an extremity of a second elongated member, the second elongated member and the female end being formed of a second continuous material; and

permanently securing the male end of the first elongated member within the female end of the second elongated member.

2. (Original): The process of claim 1 wherein formation of the female end comprises forming a hole by electrical discharge machining.

3. (Original): The process of claim 1 wherein formation of the female end comprises forming a hole by laser drilling.

4. (Original): The process of claim 1 wherein the first continuous material is different from the second continuous material.

5. (Original): The process of claim 1 wherein the first and second continuous materials comprise a biocompatible material selected from the group consisting of metals, polymers and composites.

6. (Original): The process of claim 5 wherein the group consists of stainless steel and Nitinol.

7. (Original): The process of claim 1 wherein securing the male end to the female end is selected from the group consisting of soldering, welding and gluing.

8. (Original): The process of claim 1 wherein forming the male end comprises plunge grinding.

9. (Previously presented): A guide wire for use in a medical procedure, comprising:

a first elongated member having an extremity and a male end formed at the extremity, the first elongated member formed of a first continuous material;

a second elongated member including a second extremity, the second extremity of the second elongated member including a female end, the second elongated member and the female end being formed of a second continuous material;

wherein the male end is permanently secured within the female end of a second elongated member.

10. (Previously presented): The guide wire of claim 9 wherein the female end is formed by electrical discharge machining.

11. (Previously presented): The guide wire of claim 9 wherein the female end is formed by laser drilling.

12. (Previously presented): The guide wire of claim 9 wherein the first and second continuous materials comprise biocompatible materials selected from the group consisting of metals, polymers and composites.

13. (Previously presented): The guide wire of claim 12 wherein the group consists of stainless steel and Nitinol.

14. (Previously presented): The guide wire of claim 9 wherein the male end is secured to the female end by a bond selected from the group consisting of solder, weld and glue.

15. (Previously presented): The guide wire of claim 9 wherein the male end is formed by plunge grinding.

16 – 17 (Canceled)

18. (Previously presented): A guidewire, comprising:

an elongated proximal core portion having a female end disposed at the distal extremity, the proximal core portion and female end formed from a first continuous material;

a distal core portion having a male end disposed at the proximal extremity; and

a flexible body member;

wherein the male end is permanently secured within the female end and the flexible body member is disposed about and secured to the distal core portion.

19. (Previously presented): A process for constructing a guidewire; comprising:

providing an elongated proximal core portion including a distal extremity and having a male end disposed at the distal extremity, the proximal core portion being formed from a first continuous material including stainless steel;

providing a distal core portion including a proximal extremity and having a female end with a predetermined depth disposed at the proximal extremity, the distal core portion and female end being formed from a second continuous material including a nickel-titanium alloy;

permanently securing the male end within the female end; and

disposing the flexible body member about the distal core portion.

EXHIBIT 2

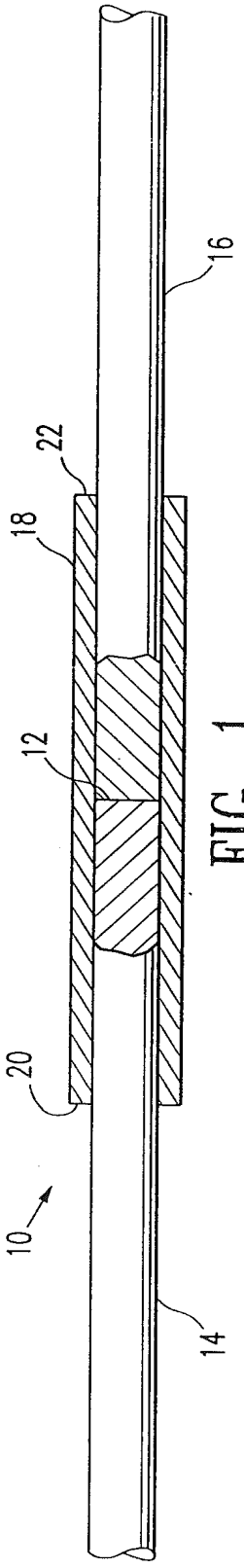

FIG. 1
PRIOR ART

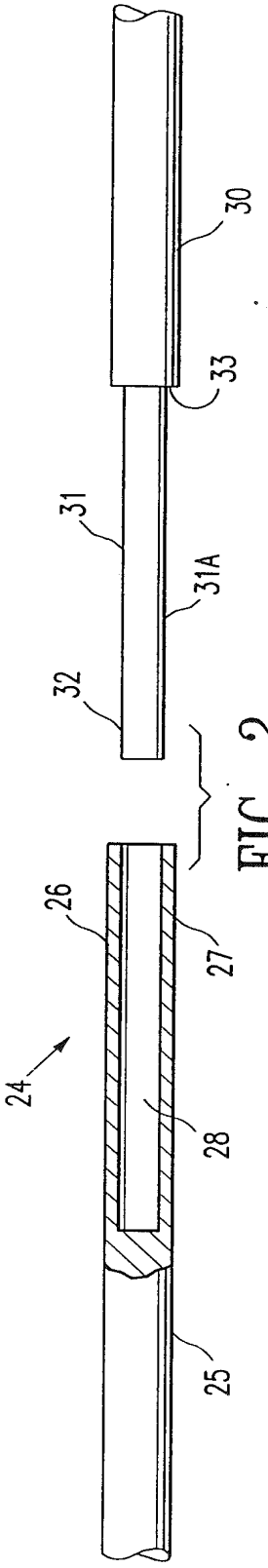

FIG. 2

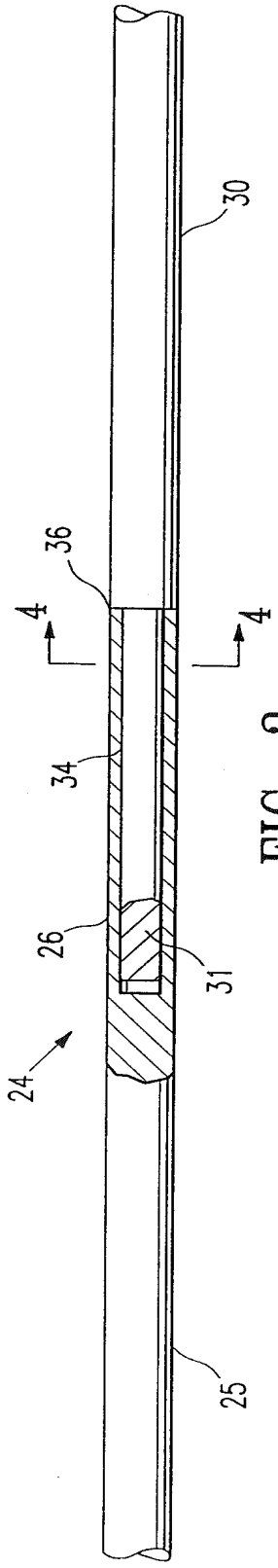

FIG. 3

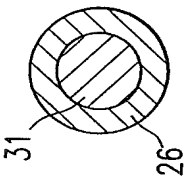

FIG. 4

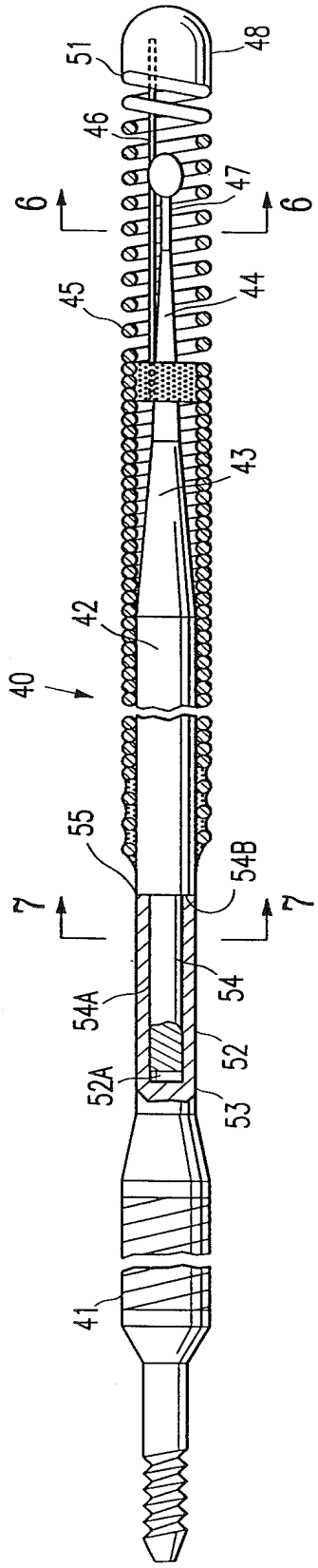

FIG. 5

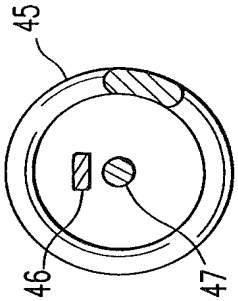

FIG. 6

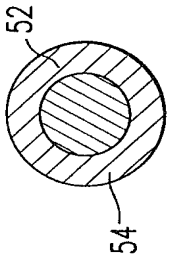

FIG. 7

EXHIBIT 3

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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Alexandria, Virginia 22313-1450
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/650,603	08/28/2003	David H. Burkett	ACS 65356 (1747D)	8329

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EXAMINER	
HONG, JOHN C	

ART UNIT	PAPER NUMBER
3726	

DATE MAILED: 11/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

FINAL REJECTION

2 - MONTH RESPONSE DUE: Jan. 27, 2007
3 - MONTH RESPONSE DUE: Feb. 27, 2007
NOTICE OF APPEAL DUE:
(6-MONTH PERIOD ENDS) May 27, 2007

Office Action Summary	Application No.	Applicant(s)	
	10/650,603	BURKETT, DAVID H.	
	Examiner	Art Unit	
	JOHN C. HONG	3726	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15,18 and 19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15,18,19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. **Claims 1,4-6,9,12,13 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Gambale et al. (U.S. Patent 5031636).**

Gambale et al. disclose : **Regarding Claims 1 and 4-6**, a process for forming a guide wire for use in a medical procedure, comprising :forming a male end (36) at an extremity of a first elongated member formed of a first continuous material; forming a female end (26) at an extremity of a second elongated member, the second elongated member and the female end being formed of a second continuous material; and permanently securing (crimping; col. 7, lines 42-44) the male end of the first elongated member within the female end of the second elongated member (Fig. 2- 4);and **Regarding Claim(s) 9,12,13 and 18**, a guide wire for use in a medical procedure, comprising: a first elongated member having an extremity and a male end (36) formed at the extremity, the first elongated member formed of a first continuous material; a second elongated member including a second extremity, the second extremity of the second elongated member including a female end (26), the second elongated member and the female end being formed of a second continuous material; wherein the male end is permanently secured (crimping; col. 7, lines 42-44) within the female end of a second elongated member (Fig. 2-4).

NOTE: Col. 7, lines 42-44 describes the guide wire **12** and extension wire **24** are **crimped** and the crimped connection maybe broken easily (col.7, lines 23-26) since the **connection is made permanently secured.**

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gambale et al. in view of Abrams et al. (U.S. Patent 5341818).

Gambale et al. teach a process for constructing a guidewire; comprising: providing an elongated proximal core portion including a distal extremity and having a male end (36) disposed at the distal extremity, the proximal core portion being formed from a first continuous material including stainless steel, providing a distal core portion including a proximal extremity and having a female end (26) with a predetermined depth disposed at the proximal extremity, the distal core portion and female end being formed from a second continuous material ; permanently securing (crimping; col. 7, lines 42-44) the male end within the female end; and disposing the flexible body member about the distal core portion (Fig. 2-4).

Gambale et al. fail to teach the distal core portion and female end being formed from a second continuous material including a nickel-titanium alloy.

Abrams et al. teach the distal core portion and female end being formed from a second continuous material including a nickel-titanium alloy (col. 4, lines 25-30).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilizing nickel-titanium alloy for forming the distal core portion and female end, as taught by Abrams et al. on the method of Gambale et al. so as to achieve stress-induced phase transformation.

NOTE: The rationale to modify or combine the prior art **does not have to be** expressly stated in the prior art; the rationale may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art, established scientific principles, or legal precedent established by prior case law. In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). See also In re Kotzab, 217 F.3d 1365, 1370, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000) (setting forth test for implicit teachings); In re Eli Lilly & Co., 902 F.2d 943, 14 USPQ2d 1741 (Fed. Cir. 1990) (discussion of reliance on legal precedent); In re Nilssen, 851 F.2d 1401, 1403, 7 USPQ2d 1500, 1502 (Fed. Cir. 1988) (references do not have to explicitly suggest combining teachings); Ex parte Clapp, 227 USPQ 972 (Bd. Pat. App. & Inter. 1985) (examiner must present convincing line of reasoning supporting rejection); and Ex parte Levengood, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993) (reliance on logic and sound scientific reasoning).

5. Claims 2,3,7,8,10,11,14,and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gambale et al. .

Gambale et al. teach the limitation except the steps of : forming hole by electrical discharge machine; laser drilling; plunge grinding; securing by soldering, welding, and gluing.

But the steps of : forming hole by electrical discharge machine; laser drilling; plunge grinding; securing by soldering, welding, gluing are well known in the art and it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the

above well known method on the process of Gambale et al. so as to manufacture more flexible guidewire.

Response to Arguments

1. Applicant's arguments filed 9/12/06 have been fully considered but they are not persuasive. See the new Office action.

Regarding applicant's arguments :

(A) That the Gambale et al. does not teach permanently securing the male end and the female end. But Gambale et al. clearly teach the connection is crimped (col.7, lines 42-44) which is permanently secure so the connection maybe easily broken. Gambale et al. further describes in col. 7, lines 11-14, 'It has been found that a connection can be made quickly and easily. It maintains sufficient tensile strength of the order of about one or two pounds force so as not to come apart during use."

(B) Objective reason has not been presented to modify Gambale et al. in view of Abrams et al. . Gambale et al. is not concerned with achieving "stress-induced phase transformation"

But the rationale to modify or combine the prior art **does not have to be** expressly stated in the prior art; the rationale may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art, established scientific principles, or legal precedent established by prior case law. In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). See also In re Kotzab, 217 F.3d 1365, 1370, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000) (setting forth test for implicit teachings); In re Eli Lilly & Co., 902 F.2d 943, 14 USPQ2d 1741 (Fed. Cir. 1990) (discussion of reliance on legal precedent); In re Nilssen, 851 F.2d 1401, 1403, 7 USPQ2d 1500, 1502 (Fed. Cir. 1988) (references do not have to explicitly suggest combining teachings); Ex parte Clapp, 227 USPQ 972 (Bd. Pat. App. & Inter. 1985) (examiner must present convincing line of reasoning supporting rejection); and Ex parte Levengood, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993) (reliance on logic and sound scientific reasoning).

(C) Abrams et al. does not teach the distal core portion and female end being formed from a second continuous material. But the Abrams et al. teach the utilizing superelastic material such as Ni-Ti type alloys on the portions of guiding members (col.4, lines 25-30; col. 4, lines 54-58), and this teaching is well known in the art.

Conclusion

2. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOHN C. HONG whose telephone number is 571-272-4529. The examiner can normally be reached on HPH.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, DAVID BRYANT can be reached on 571-272-4526. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JOHN C HONG
Primary Examiner
Art Unit 3726

Jh
November 18, 2006

EXHIBIT 4

United States Patent [19]

Gambale et al.

[11] **Patent Number: 5,031,636**

[45] **Date of Patent: * Jul. 16, 1991**

[54] **GUIDE WIRE EXTENSION**

[75] Inventors: **Richard A. Gambale**, Tyngsboro, Mass.; **James F. Crittenden**, Hollis; **James P. Ryan**, Amherst, both of N.H.

[73] Assignee: **C. R. Bard, Inc.**, Murray Hill, N.J.

[*] Notice: The portion of the term of this patent subsequent to Apr. 17, 2007 has been disclaimed.

[21] Appl. No.: **458,908**

[22] Filed: **Dec. 29, 1989**

Related U.S. Application Data

[63] Continuation of Ser. No. 19,627, Feb. 27, 1987, which is a continuation of Ser. No. 766,762, Sep. 18, 1985, abandoned.

[51] **Int. Cl.**[5] **A61B 5/00**

[52] **U.S. Cl.** **128/772**; 604/164; 604/282

[58] **Field of Search** 128/657, 772, 200.26; 604/95, 164, 166, 287, 280, 282

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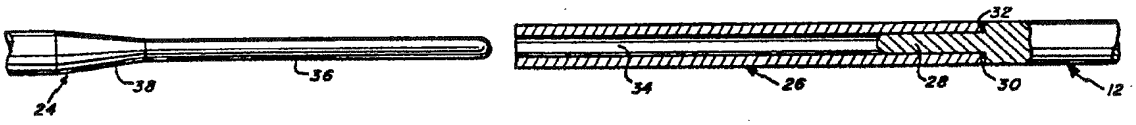
Primary Examiner—Randy Citrin Shay
Attorney, Agent, or Firm—Wolf, Greenfield & Sacks

[57] **ABSTRACT**

A guide wire system for use in catheter exchanges avoids the need for a separate exchange wire. Instead of the conventional practice in which the initial guide wire is removed and replaced with a longer exchange wire, a guide wire extension is attached to the proximal end of the initial guide wire thereby increasing its effective length so that it may be used to perform a catheter exchange. The initial guide wire remains in place in the patient's vasculature. The proximal end of the guide wire and the distal end of the exchange wire are formed to define a connection which may be crimped to effect the connection between the two wires. A crimping tool is provided to hold the mating ends of the guide wire and extension wire together while effecting the crimp.

15 Claims, 4 Drawing Sheets



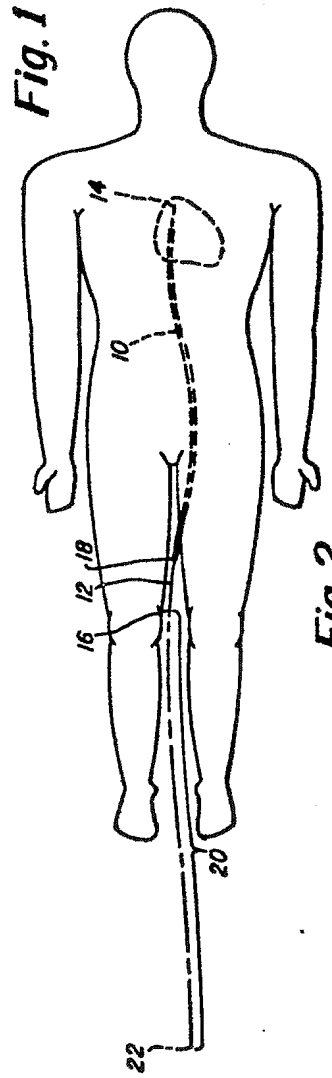


Fig. 1
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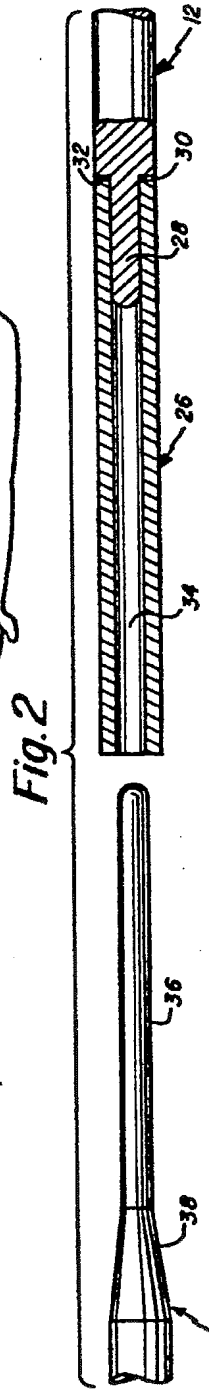
Fig. 2
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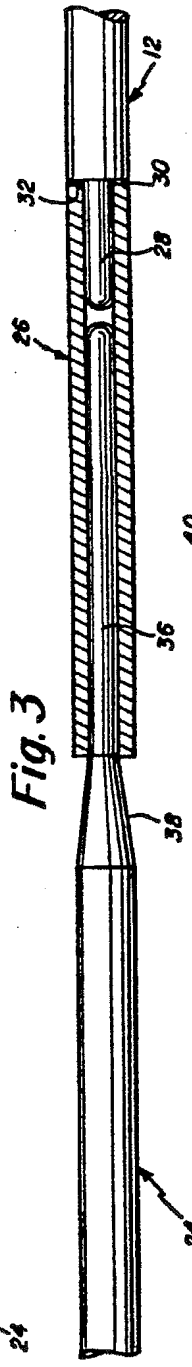
Fig. 3
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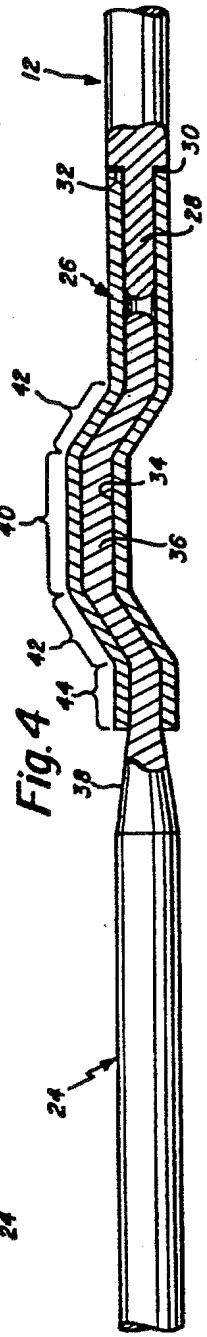
Fig. 4
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Fig. 5

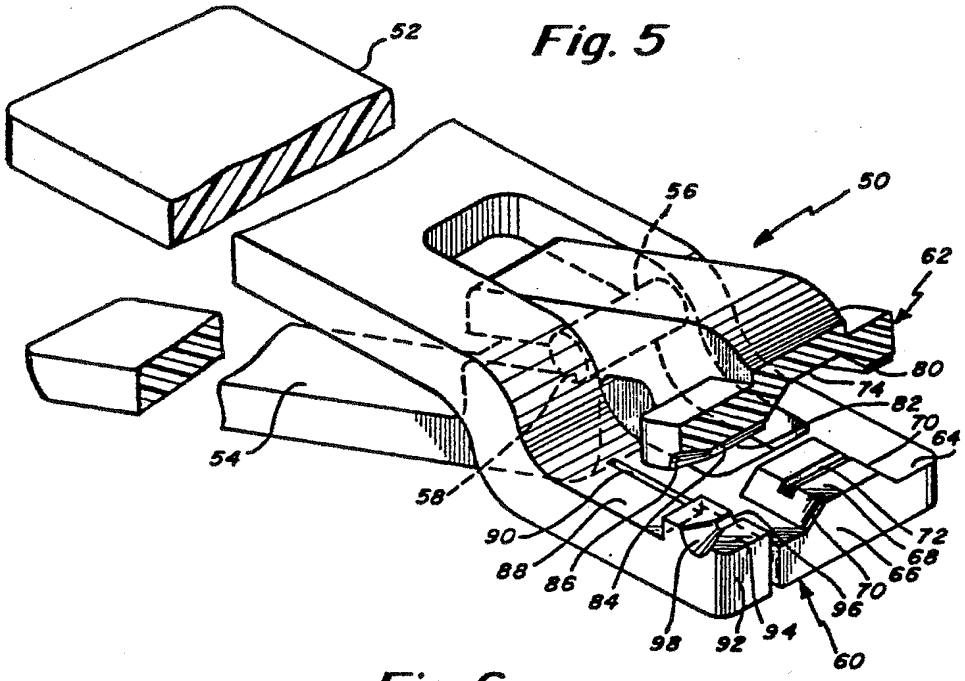
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Fig. 6

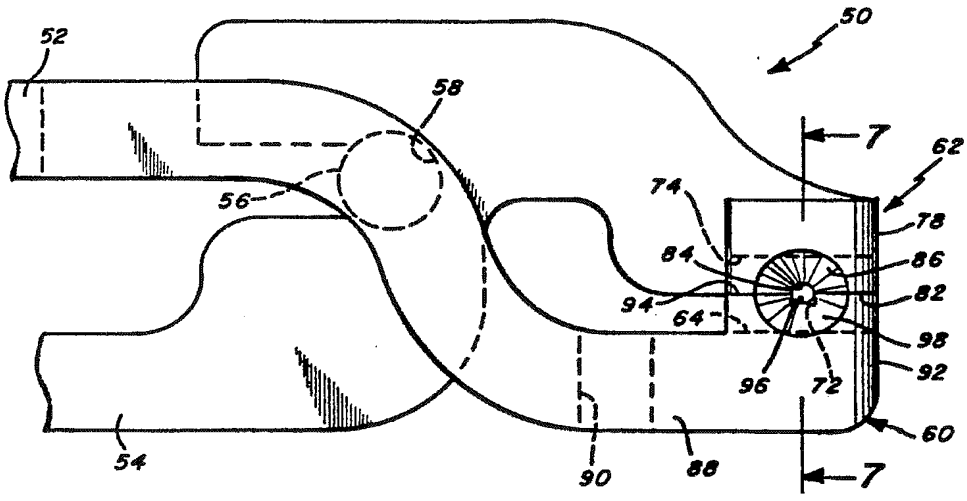
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Fig. 7

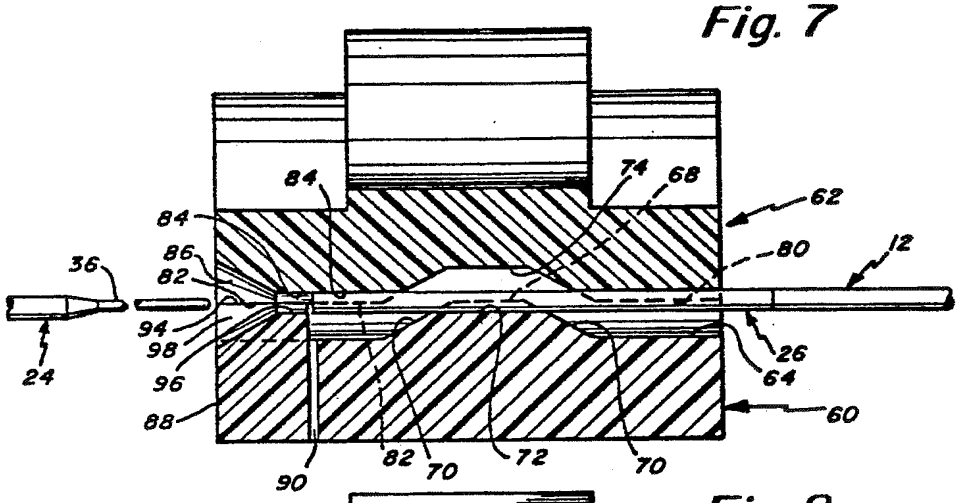


Fig. 8

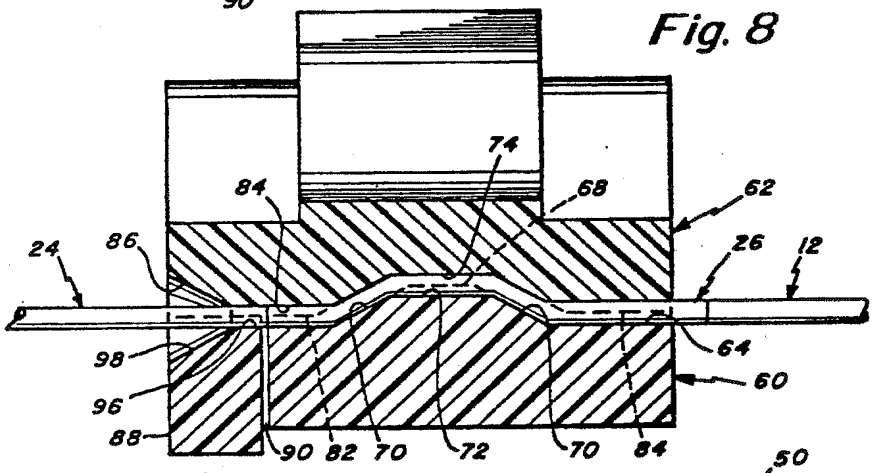
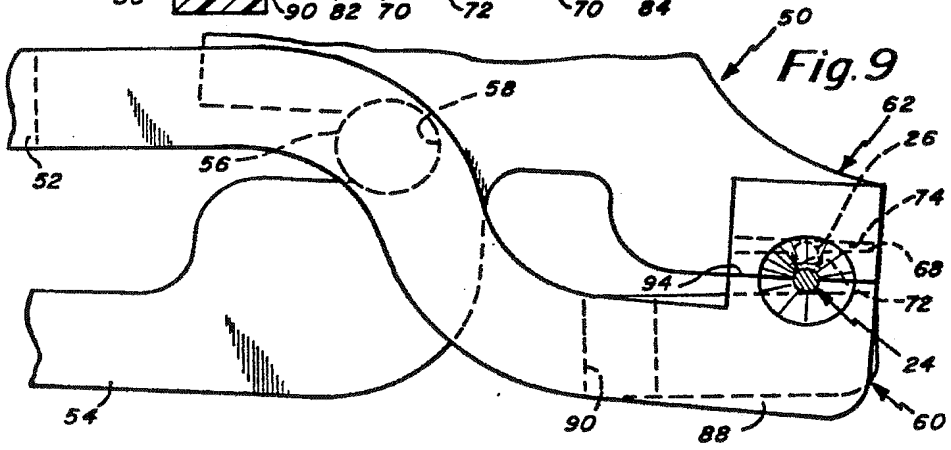


Fig. 9



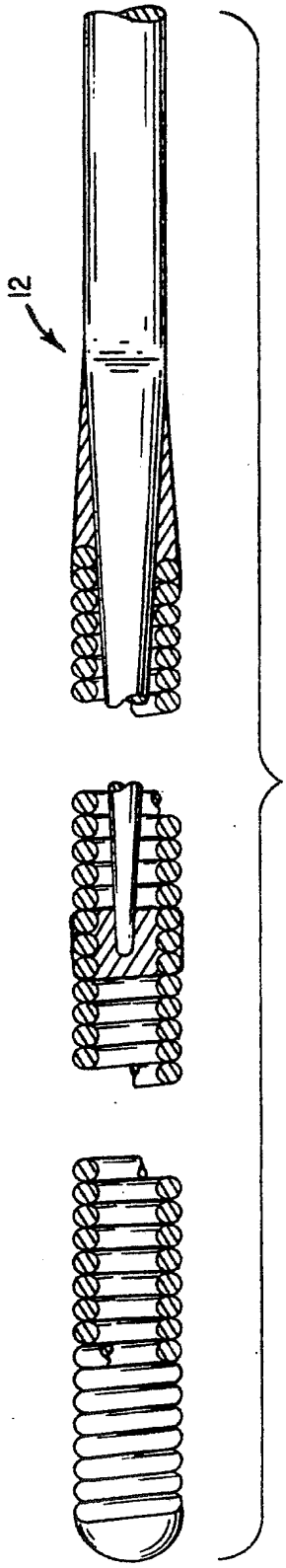


Fig. 10

GUIDE WIRE EXTENSION

This application is a continuation of U.S. application Ser. No. 019,627, now U.S. Pat. No. 4,917,103, filed 2/27/87 which is a continuation of U.S. application Ser. No. 766,762, filed Sept. 18, 1985, (now abandoned).

FIELD OF THE INVENTION

This invention relates to guide wires used in vascular catheterization procedures, and to techniques for performing catheter exchanges.

BACKGROUND OF THE INVENTION

In vascular catheterization procedures it often is necessary for the physician to use different catheters in the diagnosis or treatment of a particular blood vessel. For example, when performing a coronary angiographic study, a physician commonly will use a series of catheters, to be inserted into the patient. Each of the catheters is provided with a different shape, size or configuration suited for a specific purpose. Angiographic studies typically include the use of at least three cardiac catheters including a right coronary artery catheter, left coronary artery catheter and a pigtail catheter. The three catheters each have different shapes and configurations at their distal tips. The right and left coronary artery catheters are shaped to facilitate placement of their distal outlet tips at the entries to the right and left coronary arteries, respectively. The pigtail catheter is provided with a special pigtail-shaped tip intended to reduce trauma as the catheter is advanced through the patient's tricuspid valve into the ventricle for ventricular studies. By way of further example, other types of catheters may include balloon dilatation catheters which are intended to be placed within a stenosed portion of an artery and then inflated under high pressure to expand the lumen of the artery so as to improve blood flow through the artery. In some dilatation procedures it may be desirable to use a series of dilatation catheters having different sizes or balloon configurations.

It has long been common practice in the placement of catheters to use a guide wire which is placed in the patient's artery and which is receivable in lumen of the catheter. With a guide wire in place, a catheter can be advanced over the guide wire and thereby guided to the intended vascular site. The guide wire serves to center the catheter within the blood vessel and reduces the risk of trauma to the blood vessel by the advancing catheter. The use of a guide wire reduces the risk that the distal end of the catheter might become caught on the inner surface of the blood vessel lumen. The use of a guide wire also enables the catheter to be advanced through the blood vessel relatively quickly, thereby reducing the time required for the procedure.

A standard guide wire typically is slightly longer than the catheter with which it is to be used. For example, with an angiographic catheter of the order of 130 centimeters long, the guide wire typically may be of the order of 145–175 centimeters long. When the catheter is in place over the guide wire, a relatively short portion of the guide wire protrudes proximally from the catheter. That enables the guide wire to be manipulated, if desired, from its proximal, protruding end. In that regard, it may be noted that the guide wire may be a steerable construction in which a bend is formed in its distal tip and the direction in which the bent distal tip

extends it controlled by rotating the guide wire from its proximal end. For example, the guide wire may be of the type described in U.S. patent application Ser. No. 421,315 filed Sept. 22, 1982.

When it is necessary to change catheters, it usually is preferred that the catheter be removed in a manner which enables a guide wire to remain in place in the blood vessel so that the next succeeding catheter in the procedure can be inserted into the blood vessel, over the guide wire, and will be guided to the intended site in the blood vessel. In order to maintain a guide wire in place while withdrawing the catheter, the guide wire must be gripped at its proximal end to prevent it from being pulled out of the blood vessel together with the catheter. The catheter, however, is longer than the proximal portion of the guide wire which protrudes out of the patient. Thus, before the catheter is fully withdrawn it completely covers the proximally extending end of the guide wire. As a result, there is no means by which a standard guide wire can be held in place to prevent it from being withdrawn together with the catheter. If, as is often the case, it is desired to place the next succeeding catheter by advancing it over a guidewire, a new, longer guide wire is inserted in to the blood vessel and advanced into a position to provide a guide for the next catheter.

It is recognized generally as undesirable to insert, advance and withdraw a series of guide wires through a patient's blood vessels. To do so greatly increases the risk of trauma and puncture to the patient and also extends the duration of the procedure. It also requires exposure of the patient to additional radiation because of the additional fluoroscopy which would be required to place the successive guide wires. In order to reduce the risk of puncture or trauma it has become a long time practice to use an exchange wire when performing catheter exchanges. The exchange wire typically is about 300 centimeters long, much longer than the typical standard guide wire. The structure of the standard and exchange wires typically is the same except for the length. The additional length of the exchange wire results in a long proximally protruding portion which is longer than the catheter to be removed. When a catheter is removed some part of the proximally extending portion of the exchange wire will always be exposed to provide a means by which the exchange wire can be gripped and its position in the blood vessel maintained. Use of the exchange wire reduces the risk of trauma to the patient because it is placed while the first catheter remains in the patient. Thus, the procedure involves initially, removal of the standard guide wire from the catheter while the catheter remains in place in the patient. Then the exchange wire is advanced through the catheter to replace the original guide wire. Because the exchange wire is guided through the patient's blood vessel by the first catheter, it does not contact the lumen of the blood vessel except, perhaps, for a small portion which protruded distally of the first catheter. The original catheter then is withdrawn over the exchange wire, which is maintained is place in the blood vessel. The next succeeding catheter then can be inserted into the patient over the exchange wire.

The foregoing system and technique of using a long exchange wire has been conventional practice for many years. The use of an exchange wire during catheter exchanges, however, is not free from difficulty. The proximally extending end of the exchange wire is quite long and cannot be manipulated easily, should it be

desired to manipulate the distal end of the exchange wire. Additionally, the placement of the exchange wire must be performed under fluoroscopy to assure that it is placed properly in the patient's blood vessel. The use of an exchange wire also adds to the time and the complexity of the procedure. Notwithstanding these difficulties, the use of exchange wires has continued to be common practice in making catheter exchanges.

It is among the general objects of the invention to provide an improved guide wire system and technique by which catheter exchanges can be performed without the use of separate exchange wire and in a manner which avoids the foregoing and other difficulties.

SUMMARY OF THE INVENTION

The present invention enables a catheter exchange to be made without requiring any guide wire exchanges. In accordance with the present invention a guide wire extension is attached to the proximally extending end of the guide wire while the guide wire remains in place in the patient. The guide wire extension effectively increases the length of the guide wire. After the extension is attached to the guide wire, the catheter can be withdrawn over the guide wire and its extension. The extended length enables the proximal end of the combined guide wire and extension to be exposed at all times so that its position can be maintained during removal of the catheter. Once the first catheter has been removed, the new catheter can be inserted over the combined guide wire and extension. The technique substantially shortens the duration of the procedure because the extension can be attached to the proximal end of the guide wire much faster than a conventional wire exchange can be performed. Additionally, there is a further reduction in risk of puncturing the blood vessel. There also is less exposure to fluoroscopic radiation which is required each time a guide wire is inserted.

In accordance with the invention the proximal end of the guide wire includes a connector arrangement which may be in the form of a tubular socket. The socket is receptive to a mating tip formed at the distal end of the extension wire. When the extension wire and guide wire are mated, the joint is secured, as by crimping with a special crimping tool. In the preferred embodiment, the crimp is a trapezoidal shape and is formed to have a low profile so that it will not adversely interfere with the advancement of the catheters over the crimped joint. After a successful catheter exchange, the joint can be broken to separate the extension to allow for easy manipulation of the guide wire, from its proximal end.

It is among the objects of the invention to provide a new and improved technique for performing catheter exchanges.

Another object of the invention is to provide a guide wire system which enables catheter exchanges to be performed without the use of an exchange wire.

Another object of the invention is to provide a technique for performing catheter exchange which is quick and requires no fluoroscopic exposure.

A further object of the invention is to provide method and apparatus for attaching an extension on to the proximal end of the guide wire while the guide wire is in place thereby to facilitate catheter exchanges over the combined guide wire extension.

Another object of the invention is to provide a system of the type described in which the extension wire can be separated from the guide wire after the catheter exchange has been completed.

DESCRIPTION OF THE DRAWING

The foregoing and other objects and advantages of the invention will be appreciated more fully from the following further description thereof, with reference to the accompanying drawings wherein:

FIG. 1 is a diagrammatic illustration of a patient undergoing catheterization with a catheter inserted percutaneously into the femoral artery and showing, diagrammatically, the catheter and guide wire which protrude proximally, and illustrating further, in phantom, the relative length of an exchange wire;

FIG. 2 is a composite fragmented and partly sectional unscaled illustration of the proximal end of a guide wire of conventional length in accordance with the present invention and the guide wire extension, showing the distal end of the extension aligned with the proximal end of the guide wire in readiness to be mated;

FIG. 3 is an unscaled illustration of the proximal and distal ends of the guide wire and extension wire of the invention when mated but before being crimped;

FIG. 4 is an unscaled illustration of the crimped connection of the guide wire an extension wire;

FIG. 5 is a partly fragmented and partly sectioned illustration of the crimping tool;

FIG. 6 is a side elevation of the jaw end of the crimping tool with the jaws closed to a wire gripping position;

FIG. 7 is a sectional illustration as seen along the line 7—7 of FIG. 6 illustrating the jaws gripping the proximal end of the guide wire in readiness to receive the guide wire extension;

FIG. 8 is an illustration similar to FIG. 7 with the extension wire and guide wire connected and with the jaws of the crimping tool in a crimped configuration;

FIG. 9 is a side elevation of the jaws of the crimping tool in crimped configuration as seen along the line 9—9 of FIG. 8; and

FIG. 10 is a fragmented, partly sectional illustration of the distal end of a guide wire with which the invention may be practiced.

DESCRIPTION OF THE PREFERRED EMBODIMENT

FIG. 1 illustrates, in highly diagrammatic form, the catheter **10** and guide wire **12** which have been inserted into the patient's femoral artery and have been advanced to the region of the patient's heart where the desired procedure will be / performed. The guide wire **12** and catheter **10** will have been inserted and placed in the artery in accordance with well known procedures

When it is desired to exchange the catheter for another, it is important that the guide wire be maintained within the patient's artery so that it may guide the next succeeding catheter quickly and efficiently to the intended site in the patient's vascular system. Typically, the clearances between the guide wire **12** and inner lumen of the catheter **10**, coupled with the bends which the catheter **10** and guide wire **12** must follow along the patient's vascular system are such that withdrawal of the catheter **10** tends to drag the guide wire **12** out with the catheter **10**. In order to maintain the guide wire **12** in place while the catheter **10** is withdrawn, it is necessary to hold the guide wire **12** by its proximal end **16** while withdrawing the catheter **10** over the guide wire **12**. Because the proximal end **16** of a conventional guide wire only extends proximally beyond the proximal end **18** of the catheter by an amount which is substantially

less than the length of the catheter **10**, there is no means for retaining the conventional guide wire **12** in position while the catheter **10** is removed.

In order to effect a catheter change, it has been the practice for many years to use an exchange wire. The exchange wire is substantially longer than the conventional length of guide wire **12** and may be of the order of 300 cm long. The additional effective length of the exchange wire as compared to the conventional length guide wire **12** is represented by the phantom line **20** in FIG. **1**. The length of the exchange wire is such that its tip, represented by the reference character **22**, is spaced from the proximal end **18** of the catheter by a distance which is greater than the length of the catheter **10**.

In performing the exchange, the guide wire **12** is removed from the catheter **10** while the catheter **10** remains in the patient. The exchange wire then is inserted into and advanced along the catheter **10** until its distal tip is located at the intended site within the patient's vascular system. The additional length of the exchange wire which protrudes proximally of the proximal end **18** of the catheter **10** provides a sufficiently long means by which the exchange wire may be gripped so that its position may be maintained in the patient while the catheter **10** is withdrawn. Thus, the catheter **10** may be withdrawn over the exchange wire, and the next catheter may be placed in the patient by advancing it over and along the exchange wire. After the next catheter has been placed, it may be desirable to remove the exchange wire and replace it with another standard length guide wire, depending on the type of catheterization procedure which is to be performed. For example, if the procedure requires use of a steerable guide wire which must be manipulated from its proximal end, such a guide wire will have to be exchanged for the exchange wire after the catheter exchange has been made.

In accordance with the present invention, catheters may be exchanged without requiring removal of the guide wire **12** and without requiring the involvement attendant to the use of an exchange wire. The guide wire **12** is connected, at its proximal end, to an extension wire **24** while the guide wire **12** and catheter **10** remain in the patient. The extension wire **24** is attached securely to the proximal end of the guide wire **12** and serves to extend the effective length of the guide wire **12** sufficiently to permit the catheter **10** to be withdrawn over the guide wire **12** and extension **24**.

As shown in FIG. **2**, the guide wire **12** is provided with a hollow tubular connective fitting **26** which is attached to and extends proximally of the proximal end of the guide wire **12**. In the illustrative embodiment, the guide wire **12** is illustrated as having a proximal end formed from a solid wire such as the type of guide wire illustrated in the aforementioned U.S. patent application Ser. No. 421,315. (see FIG. **10**). It should be understood, however, that the general principles of the present invention may be applied to any guide wire by modifying the proximal end of the guide wire to include a means for attaching the proximal end of the guide wire to an extension wire.

In the illustrative embodiment, the proximal end of the guide wire is provided with a reduced diameter projection **28** which is received within an end of the tube which forms the connective fitting **26**. The tube **26** is secured to the guide wire **12** such as by brazing as indicated at **30** at the junction of the end of the tube **26** with the shoulder **32** defined at the transition of the guide wire **12** to the reduced diameter projection **28**. Alternate construction may have tapered portion to form the transition from the guide wire to the projection **28**. The outer diameter of the tube **26** preferably is the same as the outer diameter of the guide wire **12**. The tube **26** thus defines an elongated socket **34** which is receptive, as will be described, to the distal end of the extension wire **24**. The tube **26** may be formed from stainless steel, as may be the guide wire **12**. The tube **26** may be fabricated from readily available hypodermic tubing. The wall thickness of the tube **26** should be selected so that it can be crimped easily, as will be described, but it also must be capable of providing sufficient rigidity to maintain a secure connection to the guide wire extension **24**. By way of dimensional example, with a guide wire of the type described in the aforementioned U.S. patent application Ser. No. 421,315, the proximal end of the guide A wire may have an outer diameter of the order of 0.016 inches and the tubing **26** will have the same outer diameter. A wall thickness for the tubing of the order of 0.0015 to about 0.003 inches has been found to be satisfactory. The length of the tubing **26** may be of the order of about four inches and the socket may be of the order of about three inches deep.

The guide wire extension **24** also may be formed from stainless steel and preferably is of comparable diameter to that of the guide wire **12** and extension **26**. The distal end of the extension **24** has a reduced diameter tip **36** which is insertable into the socket **34** of the fitting **26**. The guide wire extension **24** may be provided with a tapered transition region **38** between its main body and the tip **36**. By way of dimensional example, in the illustrative embodiment, the tip **36** may be of the order of about four cm long having an outer diameter of 0.008–0.009 inches so that it may be received within the socket **34**. The tip **36** and socket **34** should be sufficiently long so that the full length of the tip **36** extends into the socket **34**.

FIG. **3** illustrates the manner in which the guide wire **12** and guide wire extension **24** mate. The distal tip of the extension simply is inserted into the socket **34** of the fitting **26**. The connected members then are deformed, preferably in a configuration illustrated in FIG. **4**, to secure the wire **12** and extension **24** together. Once secured, the effective length of the wire **12** will have been extended and the catheter **10** can be removed over the combined effected extended length without requiring removal of the guide wire **12**.

The mechanical attachment is effected preferably by deforming the connected tube **26** and tip **36** by displacing a segment of them laterally of the common axis X of the combined guide wire **12** and extension **24** in what may be considered as a generally U-shaped configuration. The extent of lateral displacement, however, is limited by the flexibility of the catheters with which the device is to be used. The extent of lateral displacement should not be so great or sharp so as to require so sharp a bend in the catheter that it will interfere with smooth advancement of the catheter **10** over the joint. In accordance with the present invention, it has been found that a trapezoidal shaped deformation seems to provide the best results, although other non-trapezoidal shapes might be employed. As shown in FIG. **4**, the preferred shape of the crimp includes a central segment **40** and a pair of spaced segments **42** which are formed between the ends of the tube **26**. Preferably the crimp is formed in a manner which leaves a short proximal segment **44** of the tubing **26** which remains in coaxial alignment

with the extension wire 24. In the preferred embodiment, the spaced segments 42 are arranged at an angle A of about 30° to the central axis of the guide wire 12 and extension 24. The central crimped segment 42 is displaced transversely of the axis X but extends substantially parallel to it. Preferably, the central segment 40 can be displaced about 0.060 inches the common axis X. The overall length of the crimp including the end segments 42 and central segments is of the order of about 0.60 inches.

It has been found that such a connection can be made quickly and easily. It maintains sufficient tensile strength of the order of about one to two pounds force so as not to come apart during use, yet it does not interfere with advancement of the catheter as it is snaked over the crimped portion. Additionally, it should be noted that the connection also maintains sufficient compressive strength so that when the catheter is advanced over the guide wire and extension, the connection between the guide wire and guide wire extension will not collapse or otherwise become adversely deformed as a result of the compressive force resulting from pushing the catheter along the guide wire extension. Additionally, the connection may be broken easily and quickly should it be desired to separate the guide wire extension 24 from the guide wire 12. The guide wire 12, fitting 26 and guide wire extension 24 preferably all are coated with a thin film of low-friction material such as polytetrafluoroethylene to enhance the ease with which the catheter may slide over the guide wire and connected extension.

Although the principles of the invention may be applied to a wide range of sizes-of guide wires and catheters, the configuration in the illustrative embodiment is useful particularly with smaller diameter guide wires for use with relatively small diameter flexible catheters. For example, the illustrative embodiment of the invention is particularly advantageous when used with guide wires of the order of 0.025 diameter and smaller which, in turn, may be used with catheters of the order of 6 French and smaller.

The invention also provides a device for facilitating connection and crimping of the connected guide wire 12 and extension wire 24. As shown in FIGS. 5-9, the crimping device indicated generally at 50 may be molded from a suitable plastic such as for example, Delrin (trade name for acetal). The crimping device 50 is somewhat in the form of pliers having a pair of handle members 52, 54 which are connected to each other at a pivot pin 56 and slot 58 formed integrally with the members 52, 54. The members 52, 54 thus are pivotable with respect to each other and define a pair of jaw members 60, 62 which are movable toward and away from each other. The jaws 60, 62 are arranged to hold the connective fitting 26 at the proximal end of the guide wire 12 in a position to receive the tip 36 of the extension wire 24. The jaws 60, 62 also include an arrangement for guiding the tip 56 of the extension wire 24 into the socket 34 of the fitting 26 and, when the extension wire and fitting 26 are mated, for effecting the crimp illustrated in FIG. 4.

One of the jaw members 60 has an inner face 64. The jaw 60 is molded to include a platform 66 which extends away from the jaw face 64. The platform is of trapezoidal configuration and includes an upper face 68 which is parallel to the inner face 64 of the jaw 60, and a pair of sloping side faces 70. The transversely extending groove 72 is formed transversely along the upper face 68 of the platform 66. The groove 72 is intended to receive and cooperate in holding the connective fitting 26. The opposing jaw 62 is formed with a trapezoidal shaped indentation 74 having surfaces corresponding to and paralleling those of the platform 66, including surfaces 70 and 72. The jaw member 62 also includes a pair of transversely extending members 76, 78 which have surfaces 80, 82. The surfaces 80, 82 extend parallel to the surface 64 of member 52 when the jaws 60, 62 are mated. As will be described in further detail, the fitting 26 may be positioned in the device by placing it along the channel 72 and then closing the jaw 62 to cause jaw surfaces 80 and 82 to engage the fitting 26 and hold it in place, ready to receive the tip 36 of the extension wire 24. The surface 82 of the jaw member 62 is provided with a transversely extending groove 84 which receives the end of the fitting 26 in a manner and for a purpose which will be described. The outer end of the groove 84 is formed to include an upwardly and transversely diverging funnel-shaped channel 86.

The jaw end of the handle member 52 includes an integrally formed elongate finger 88 which is separated from the main portion of the jaw member 60 by a slot 90. The finger is formed so that it may flex and bend with respect to the jaw 60 and handle 52. The outer end of the finger 88 is formed to include a platform 92 having an upper surface 94. The platform 92 includes a transversely extending groove 96 which communicates with transversely opening funnel-shaped channel 98. The platform 92 is located with respect to the transverse portion 78 of the jaw 62 so that when the jaws 60, 62 are brought together, the surfaces 82 and 94 will butt against each other with the grooves 84, 96 cooperating to define a guiding passage and the channels 86, 98 cooperating to define a funnel leading into the guiding passage.

As shown in FIGS. 6 and 7 the connective fitting 26 is held between the jaws 60, 62 with the fitting 26 being engaged by the channel 72 on the platform 66 and by the surfaces 80 and groove 84 of the jaw member 62. The fitting 26 thus is held securely and its socket 34 is in alignment with the guiding passage defined by the cooperating grooves 84, 96. The distal tip 36 of the extension wire 24 then may be passed through the funnel 86 and into the aligned socket 34. The funnel defined by the channels 86, 98 serves to facilitate entry of the tip 36 into the socket 34.

Once the distal tip 36 of the extension wire has been inserted through the funnel and guiding passage into the socket 34, the crimping tool is operated to draw the jaws 60, 62 together and effect the crimping operation. During the crimping operation, the finger 88 flexes downwardly as shown in FIG. 7 to maintain the axial alignment of the guide wire 12 and extension wire 24 which are located proximally and distally of the crimp. After the crimp has been completed, the jaws 60, 62 are opened to release the connected wires 12, 24. The guide wire 12 thus has been effectively extended so that the catheter 10 may be removed without requiring withdrawal of the guide wire 12 and insertion of a new exchange wire. After the extension has been attached and the catheter has been withdrawn, the next succeeding catheter is advanced over the extension and the guide wire into and through the patient's blood vessel. Depending on the technique involved and the physician's preference, the extension may be permitted to remain attached to the guide wire or may be separated

easily. Separation can be effected by cutting the guide wire distaily of the crimp.

From the foregoing, it will be appreciated that the invention provides a technique and devices by which catheter exchanges may be made in a manner which shortens the time required for the procedure, reduces the amount of radiation exposure to the patient and reduces further the risk of trauma to the patient. It should be understood, however, that the foregoing description of the invention is intended merely to be illustrative thereof and other embodiments and modifications may be apparent to those skilled in the art without departing from its spirit.

Having thus described the invention, what I desire to claim and secure by letters patent is:

1. A guide wire system for guiding an elongated, flexible catheter having a guide wire lumen through a lumen in the body of a patient and adapted to facilitate exchange of the catheter for another catheter comprising:

a guide wire having a proximal end and a distal end;

an extension wire having a proximal end and a distal end;

a connector element on at least one of said wires for connection of the proximal end of the guide wire with the distal end of the extension wire thereby to extend the effective length of the guide wire;

said wires being connected by said connector element;

said connector element being constructed and arranged to be received within the catheter lumen and to have a low profile in which its cross-sectional dimensions are substantially the same as those of the wires to enable the catheter to be passed over the wires and the connector element when the wires are connected by the connector element;

whereby a catheter placed in a patient and having the guide wire extending therethrough may be exchanged for another catheter by connecting the proximal end of the guide wire with the distal end of the extension wire, then removing the catheter over the connected wires and then advancing another catheter onto and along the wires without requiring removal or substantial change of position of the guide wire; the connector element being constructed so that the connection between the wires has sufficient compressive strength to permit said catheter exchange.

2. A guide wire system as defined in claim 1 further comprising, in combination, a flexible catheter through which the guide wire and extension wire are slidably received, and wherein the combined length of the guide wire and the extension wire is approximately twice the length of the catheter.

3. A guide wire system as defined in claim 1 further comprising:

the connection between the proximal end of the guidewire and the distal end of the extension wire being sufficiently strong as to withstand an axial separation force of the order of one pound.

4. A guide wire system as defined in claim 1 wherein the connector element comprises a tubular socket attached on an end of said at least one of said wires and wherein an end of the other of said wires is dimensioned to be received within the tubular socket.

5. A guide wire system as defined in claim 1 further comprising:

the connector element being round in cross-section and having a diameter no greater than that of the guide wire.

6. In a guide wire adapted for guiding an elongate, flexible catheter having a guide wire lumen through a lumen in the body of a patient, the guide wire having proximal and distal ends, the improvement comprising connector means at the proximal end of the guide wire for connecting the end of another wire to the proximal end of the guide wire whereby a catheter placed in a patient and having the guide wire extending therethrough may be exchanged for another catheter by connecting the proximal end of the guide wire with the distal end of said another wire then removing the catheter over the connected wires and then advancing another catheter onto and along the wires without requiring removal or substantial change of position of the guide wire.

7. A guide wire system for guiding an elongate flexible catheter having a guide wire lumen through a lumen in the body of a patient comprising:

a guide wire having a proximal end and a distal end, the guide being formed at least in part by an elongate helical coil extending along the length of the guide wire;

an extension wire having a proximal end and a distal end;

connector means for connection of the proximal end of the guide wire with the distal end of the extension wire thereby to extend the effective length of the guide wire;

said connector means being constructed and arranged to be received within the catheter lumen and to enable the catheter to be passed over the wires and the connector means when the wires are connected by the connector means.

8. An extendable guide wire system for use in connection with a catheter insertable into the body of a patient comprising:

a main guide wire section adapted to be inserted into the patient's body, the main guide wire section having a proximal mating end adapted to extend out of the patient's body and a distal end adapted to extend into the patient's body;

a guide wire extension section having a mating end; and

a connection therebetween including a tubular member on the mating end of one of the guide wire sections, the tubular member having an open end, and a male member on the mating end of the other guide wire section, the male member being adapted to be manually inserted into the open end of the tubular member and to be detachably secured to the tubular member to detachably connect the two sections together.

9. An extendable guide wire system as defined in claim 8 further comprising, in combination, a flexible catheter through which the main guide wire section and the guide wire extension section are slidably received and wherein the combined length of the main guide wire section and guide wire extension section is approximately twice the length of the catheter.

10. A guide wire system as defined in claim 8 wherein the connection between the main guide wire section and guide wire extension section is sufficiently strong to withstand an axial separation force of the order of one pound.

11. An extendable guidewire system as defined in claim 8 wherein the connection between the guidewire sections further comprises:

the mated male and tubular members being deformed transversely into a generally U-shaped configuration.

12. A guidewire system as defined in claim 11 wherein said U-shaped configuration is generally trapezoidal, having a central segment and a pair of sloped end segments.

13. In a guide wire adapted for guiding an elongate flexible catheter having a guide wire lumen through a lumen in the body of a patient, the guide wire having proximal and distal ends, the improvement comprising a connector element at the proximal end of the guide wire, the connector element having cross sectional dimensions not greater than that of the guidewire and being in the form of a tubular socket or in the form of a projection of smaller cross sectional dimensions than that of the guide wire for connecting the end of another wire to the proximal end of the guide wire whereby a catheter placed in a patient and having the guide wire extending therethrough may be exchanged for another catheter by connecting the proximal end of the guide wire with the distal end of said another wire, then removing the catheter over the connected wires, and then advancing another catheter onto and along the wires without requiring removal or substantial change of position of the guide wire.

14. A guide wire as defined in claim 13 wherein the connector element comprises a tubular socket.

15. A guide wire as defined in claim 13 wherein the connector element comprises a reduced diameter element insertable into a tubular socket.

* * * * *

EXHIBIT 5

US005341818A

United States Patent [19]

Abrams et al.

[11] Patent Number: 5,341,818

[45] Date of Patent: Aug. 30, 1994

[54] GUIDEWIRE WITH SUPERELASTIC DISTAL PORTION

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[73] Assignee: **Advanced Cardiovascular Systems, Inc.**, Santa Clara, Calif.

[21] Appl. No.: **994,679**

[22] Filed: **Dec. 22, 1992**

[51] **Int. Cl.**[5] **A61B 5/00**

[52] **U.S. Cl.** **128/772**

[58] **Field of Search** 128/657, 772; 604/95, 604/280–283

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Primary Examiner—Max Hindenburg

Attorney, Agent, or Firm—Crosby, Heafey, Roach & May

[57] **ABSTRACT**

An improved guidewire for advancing a catheter within a body lumen which has a high strength proximal portion, a distal portion formed of superelastic alloy and a connector formed of superelastic alloy to provide a torque transmitting coupling between the distal end of the proximal portion and the proximal end of the distal portion. The superelastic alloy elements are preferably cold worked and then heat treated at a temperature well above the austenite-to-martensite transformation temperature, while being subjected to longitudinal stresses equal to about 5 to about 50% of the room temperature yield stress to impart to the metal a straight "memory". The guiding member using such improved material exhibits a stress induced austenite-to-martensite phase transformation at an exceptionally high constant yield strength of at least 70 ksi for solid members and at least 50 ksi for tubular members with a broad recoverable strain of at least about 4% during the phase transformation.

24 Claims, 1 Drawing Sheet

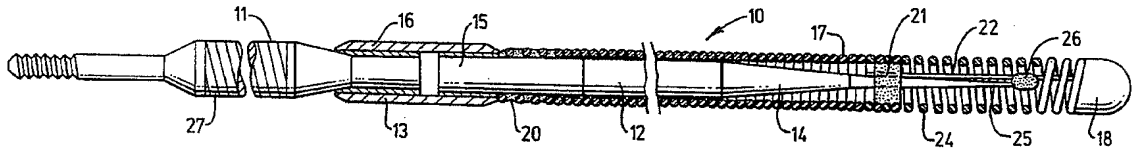

FIG. 1

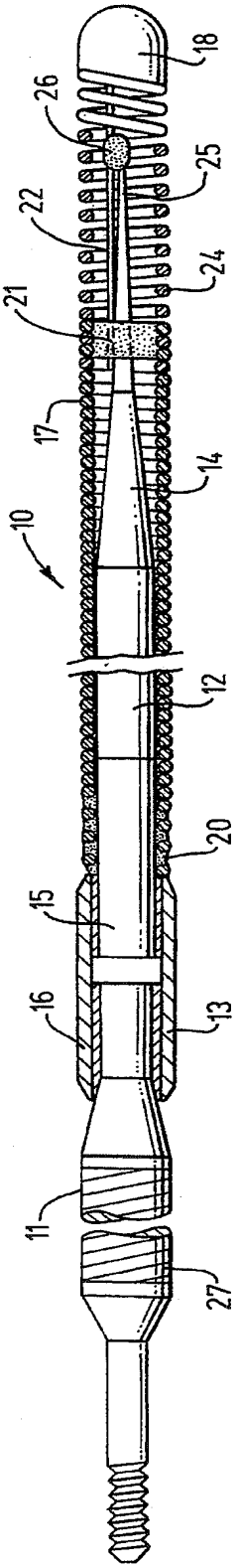
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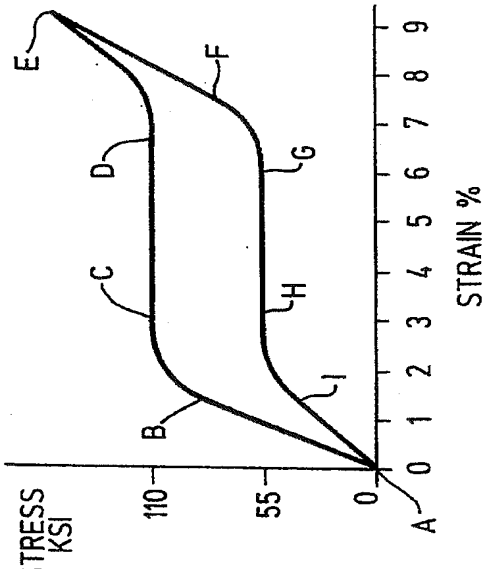
FIG. 2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GUIDEWIRE WITH SUPERELASTIC DISTAL PORTION

BACKGROUND OF THE INVENTION

This invention relates to the field of medical devices, and more particularly to guiding means such as a guidewire for advancing a catheter within a body lumen in a procedure such as percutaneous transluminal coronary angioplasty (PTCA).

In a typical PTCA procedure a guiding catheter having a preformed distal tip is percutaneously introduced into the cardiovascular system of a patient in a conventional Seldinger technique and advanced therein until the distal tip of the guiding catheter is seated in the ostium of a desired coronary artery. A guidewire is positioned within an inner lumen of a dilatation catheter and then both are advanced through the guiding catheter to the distal end thereof. The guidewire is first advanced out of the distal end of the guiding catheter into the patient's coronary vasculature until the distal end of the guidewire crosses a lesion to be dilated, then the dilatation catheter having an inflatable balloon on the distal portion thereof is advanced into the patient's coronary anatomy over the previously introduced guidewire until the balloon of the dilatation catheter is properly positioned across the lesion. Once in position across the lesion, the balloon is inflated to a predetermined size with radiopaque liquid at relatively high pressures (e.g. greater than 4 atmospheres) to compress the arteriosclerotic plaque of the lesion against the inside of the artery wall and to otherwise expand the inner lumen of the artery. The balloon is then deflated so that blood flow is resumed through the dilated artery and the dilatation catheter can be removed therefrom.

Conventional guidewires for angioplasty and other vascular procedures usually comprise an elongated core member with one or more tapered sections near the distal end thereof and a flexible body such as a helical coil disposed about the distal portion of the core member. A shapable member, which may be the distal extremity of the core member or a separate shaping ribbon which is secured to the distal extremity of the core member extends through the flexible body and is secured to a rounded plug at the distal end of the flexible body. Torquing means are provided on the proximal end of the core member to rotate, and thereby steer, the guidewire while it is being advanced through a patient's vascular system.

Further details of dilatation catheters, guidewires, and devices associated therewith for angioplasty procedures can be found in U.S. Pat. No. 4,323,071 (Simpson-Robert); U.S. Pat. No. 4,439,185 (Lundquist); U.S. Pat. No. 4,516,972 (Samson); U.S. Pat. No. 4,538,622 (Samson et al.); U.S. Pat. No. 4,554,929 (Samson et al.); U.S. Pat. No. 4,616,652 (Simpson); and U.S. Pat. No. 4,638,805 (Powell) which are hereby incorporated herein in their entirety by reference thereto.

Steerable dilatation catheters with fixed, built-in guiding members, such as described in U.S. Pat. No. 4,582,181 (now Re 33,166) are frequently used because they have lower deflated profiles than conventional over-the-wire dilatation catheters and a lower profile allows the catheter to cross tighter lesions and to be advanced much deeper into a patient's coronary anatomy.

A major requirement for guidewires and other guiding members, whether they be solid wire or tubular

members, is that they have sufficient column strength to be pushed through a patient's vascular system or other body lumen without kinking. However, they must also be flexible enough to avoid damaging the blood vessel or other body lumen through which they are advanced. Efforts have been made to improve both the strength and flexibility of guidewires to make them more suitable for their intended uses, but these two properties are for the most part diametrically opposed to one another in that an increase in one usually involves a decrease in the other.

The prior art makes reference to the use of alloys such as Nitinol (Ni—Ti alloy) which have shape memory and/or superelastic characteristics in medical devices which are designed to be inserted into a patient's body. The shape memory characteristics allow the devices to be deformed to facilitate their insertion into a body lumen or cavity and then be heated within the body so that the device returns to its original shape. Superelastic characteristics on the other hand generally allow the metal to be deformed and restrained in the deformed condition to facilitate the insertion of the medical device containing the metal into a patient's body, with such deformation causing the phase transformation. Once within the body lumen the restraint on the superelastic member can be removed, thereby reducing the stress therein so that the superelastic member can return to its original undeformed shape by the transformation back to the original phase.

Alloys having shape memory/superelastic characteristics generally have at least two phases, a martensite phase, which has a relatively low tensile strength and which is stable at relatively low temperatures, and an austenite phase, which has a relatively high tensile strength and which is stable at temperatures higher than the martensite phase.

Shape memory characteristics are imparted to the alloy by heating the metal at a temperature above which the transformation from the martensite phase to the austenite phase is complete, i.e. a temperature above which the austenite phase is stable. The shape of the metal during this heat treatment is the shape "remembered". The heat treated metal is cooled to a temperature at which the martensite phase is stable, causing the austenite phase to transform to the martensite phase. The metal in the martensite phase is then plastically deformed, e.g. to facilitate the entry thereof into a patient's body. Subsequent heating of the deformed martensite phase to a temperature above the martensite to austenite transformation temperature causes the deformed martensite phase transform to the austenite phase and during this phase transformation the metal reverts back to its original shape.

The prior methods of using the shape memory characteristics of these alloys in medical devices intended to be placed within a patient's body presented operational difficulties. For example, with shape memory alloys having a stable martensite temperature below body temperature, it was frequently difficult to maintain the temperature of the medical device containing such an alloy sufficiently below body temperature to prevent the transformation of the martensite phase to the austenite phase when the device was being inserted into a patient's body. With intravascular devices formed of shape memory alloys having martensite-to-austenite transformation temperatures well above body temperature, the devices could be introduced into a patient's

body with little or no problem, but they had to be heated to the martensite-to-austenite transformation temperature which was frequently high enough to cause tissue damage and very high levels of pain.

When stress is applied to a specimen of a metal such as Nitinol exhibiting superelastic characteristics at a temperature at or above which the transformation of martensite phase to the austenite phase is complete, the specimen deforms elastically until it reaches a particular stress level where the alloy then undergoes a stress-induced phase transformation from the austenite phase to the martensite phase. As the phase transformation proceeds, the alloy undergoes significant increases in strain but with little or no corresponding increases in stress. The strain increases while the stress remains essentially constant until the transformation of the austenite phase to the martensite phase is complete. Thereafter, further increase in stress are necessary to cause further deformation. The martensitic metal first yields elastically upon the application of additional stress and then plastically with permanent residual deformation.

If the load on the specimen is removed before any permanent deformation has occurred, the martensitic specimen will elastically recover and transform back to the austenite phase. The reduction in stress first causes a decrease in strain. As stress reduction reaches the level at which the martensite phase transforms back into the austenite phase, the stress level in the specimen will remain essentially constant (but substantially less than the constant stress level at which the austenite transforms to the martensite) until the transformation back to the austenite phase is complete, i.e. there is significant recovery in strain with only negligible corresponding stress reduction. After the transformation back to austenite is complete, further stress reduction results in elastic strain reduction. This ability to incur significant strain at relatively constant stress upon the application of a load and to recover from the deformation upon the removal of the load is commonly referred to as superelasticity or pseudoelasticity.

The prior art makes reference to the use of metal alloys having superelastic characteristics in medical devices which are intended to be inserted or otherwise used within a patient's body. See for example, U.S. Pat. No. 4,665,905 (Jervis) and U.S. Pat. No. 4,925,445 (Sakamoto et al.).

The Sakamoto et al. patent discloses the use of a nickel-titanium superelastic alloy in an intravascular guidewire which could be processed to develop relatively high yield strength levels. However, at the relatively high yield stress levels which cause the austenite-to-martensite phase transformation characteristic of the material, it did not have a very extensive stress-induced strain range in which the austenite transforms to martensite at relative constant stress. As a result, frequently as the guidewire was being advanced through a patient's tortuous vascular system, it would be stressed beyond the superelastic region, i.e. develop a permanent set or even kink which can result in tissue damage. This permanent deformation would generally require the removal of the guidewire and the replacement thereof with another.

Products of the Jervis patent on the other hand had extensive strain ranges, i.e. 2 to 8% strain, but the relatively constant stress level at which the austenite transformed to martensite was very low, e.g. 50 ksi.

In copending application Ser. No. 07/629,381, filed Dec. 18, 1990 entitled Superelastic Guiding Member, guide wires or guiding members are described which have at least a solid or tubular portion thereof exhibiting superelastic characteristics including an extended strain region over a very high, relatively constant high stress level which effects the austenite transformation to martensite. While the properties of the guidewire formed of the superelastic material were very advantageous, it was found that the guidewires and guiding members formed of materials having superelastic characteristics did not have optimum push and torque characteristics.

SUMMARY OF THE INVENTION

The present invention is directed to improve guidewires or guiding members, wherein the distal portion is provided with superelastic characteristics resulting from the stress-induced transformation of austenite to martensite and wherein the proximal portion is provided with high strength elastic materials.

The guidewire or guiding member of the invention has a high strength proximal section with a high strength distal section with superelastic properties and a connector element between the proximal and distal sections which has superelastic properties to provide a smooth transition between the proximal and the distal sections. In a presently preferred embodiment the guidewire or guiding member has a solid core distal section formed of superelastic materials such as NiTi type alloys and the connector is a hollow tubular shaped member which has a inner passageway adapted to receive the proximal end of the solid core distal section.

The superelastic distal core member and the hollow connector of the invention exhibit stress-induced phase transformation at body temperature (about 37° C.) at a stress level well above about 50 ksi, preferably above 70 ksi and in many cases above about 90 ksi. The complete stress-induced transformation of the austenite phase to the martensite phase causes a strain in the specimen of at least about 4%, preferably over 5%. The region of phase transformation resulting from stress preferably begins when the specimen has been strained about 2 to 3% at the onset of the phase change from austenite to martensite and extends to about 7 to about 9% strain at the completion of the phase change. The stress and strain referred to herein is measured by tensile testing. The stress-strain relationship determined by applying a bending moment to a cantilevered specimen is slightly different from the relationship determined by tensile testing because the stresses which occur in the specimen during bending are not as uniform as they are in tensile testing. There is considerably less change in stress during the phase transformation than either before or after the stress-induced transformation. The stress level is relatively constant within the transformation period.

The portions of the guiding member having superelastic properties is preferably formed from an alloy consisting essentially of about 30 to about 52% titanium and the balance nickel and up to 10% of one or more additional alloying elements. Such other alloying elements may be selected from the group consisting of up to 3% each of iron, cobalt, platinum, palladium and chromium and up to about 10% copper and vanadium. As used herein all references to percent composition are atomic percent unless otherwise noted.

To form the elongated superelastic portion of the guiding member, elongated solid rod or tubular stock of the preferred alloy material is first cold worked, preferably by drawing, to effect a size reduction of about 30% to about 70% in the transverse cross section thereof.

The cold worked material may then be given a memory imparting heat treatment at a temperature of about 350° to about 600° C. for about 0.5 to about 60 minutes, while maintaining a longitudinal stress on the elongated portion equal to about 5% to about 50%, preferably about 10% to about 30%, of the yield stress of the material (as measured at room temperature). This thermomechanical processing imparts a straight "memory" to the superelastic portion and provides a relatively uniform residual stress in the material. Another method involves mechanically straightening the wire after the cold work and then heat treating the wire at temperatures between about 300° and about 450° C., preferably about 330° to about 400° C. The latter treatment provides substantially higher tensile properties. The cold worked and heat treated alloy material has an austenite finish transformation temperature less than body temperature and generally about −10° C. to about 30° C. For more consistent final properties, it is preferred to fully anneal the solid rod or tubular stock prior to cold work so that the material will always have the same metallurgical structure at the start of the cold working and so that it will have adequate ductility for subsequent cold working. It will be appreciated by those skilled in the art that means of cold working the metal other than drawing, such as rolling or swaging, can be employed. The constant yield stress levels for tubular products have been found to be slightly lower than the levels for solid products. For example, superelastic wire material of the invention will have a constant stress level usually above about 70 ksi, preferably above about 90 ksi, whereas, superelastic tubing material will have a constant stress level of above 50 ksi, preferable above about 70 ksi. The ultimate tensile strength of both forms of the material is well above 200 ksi with an ultimate elongation at failure of about 15%.

The elongated superelastic members of the invention exhibit stress-induced austenite-to-martensite phase transformation over a broad region of strain at a very high, relatively constant stress levels. As a result a guiding member having a distal portion formed of this material is very flexible, it can be advanced through very tortuous passageways such as a patient's coronary vasculature with little risk that the superelastic portion of the guiding member will develop a permanent set and at the same time it will effectively transmit the torque applied thereto without causing the guiding member to whip. The high strength proximal portion of the guidewire or guiding member provides excellent pushability and torquability to the guidewire or guiding member.

These and other advantages of the invention will become more apparent from the following detailed description thereof when taken in conjunction with the following exemplary drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is an elevational view of a guidewire which embodies features of the invention.

FIG. 2 is a schematic, graphical illustration of the stress-strain relationship of superelastic material.

DETAILED DESCRIPTION OF THE INVENTION

FIG. 1 illustrates a guidewire **10** embodying features of the invention that is adapted to be inserted into a patient's body lumen, such as an artery. The guidewire **10** comprises an elongated, relatively high strength proximal portion **11**, a relatively short distal portion **12** which is formed substantially of superelastic alloy material and a connector element **13** which is formed substantially of superelastic alloy material and which connects the proximal end of the distal portion **12** to the distal end of the proximal portion **11** into a torque transmitting relationship. The distal portion **12** has at least one tapered section **14** which becomes smaller in the distal direction. The connector element **13** is a hollow tubular shaped element having an inner lumen extending therein which is adapted to receive the proximal end **15** of the distal portion **12** and the distal end **16** of the proximal portion **11**. The ends **15** and **16** may be press fit into the connector element or they may be secured therein by crimping or swaging the connector or by means such as a suitable adhesive or by welding, brazing or soldering.

A helical coil **17** is disposed about the distal portion **12** and has a rounded plug **18** on the distal end thereof. The coil **17** is secured to the distal portion **12** at proximal location **20** and at intermediate location **21** by a suitable solder. A shaping ribbon **22** is secured by its proximal end to the distal portion **12** at the same location **21** by the solder and by the distal end thereof to the rounded plug **18** which is usually formed by soldering or welding the distal end of the coil **17** to the distal tip of the shaping ribbon **22**. Preferably, the most distal section **24** of the helical coil **17** is made of radiopaque metal such as platinum or platinum-nickel alloys to facilitate the observation thereof while it is disposed within a patient's body. The most distal section **24** should be stretched about 10 to about 30%.

The most distal part **25** of the distal portion **12** is flattened into a rectangular section and preferably provided with a rounded tip **26**, e.g. solder to prevent the passage of the most distal part through the spacing between the stretched distal section **24** of the helical coil **17**.

The exposed portion of the elongated proximal portion **11** should be provided with a coating **27** of lubricous material such as polytetrafluoroethylene (sold under the trademark Teflon by du Pont, de Nemours & Co.) or other suitable lubricous coatings such as the polysiloxane coatings disclosed in co-pending application Ser. No. 559,373, filed Jul. 24, 1990 which is hereby incorporated by reference.

The elongated proximal portion **11** of the guidewire **10** is generally about 130 to about 140 cm in length with an outer diameter of about 0.006 to 0.018 inch for coronary use. Larger diameter guidewires may be employed in peripheral arteries and other body lumens. The lengths of the smaller diameter and tapered sections can range from about 2 to about 20 cm, depending upon the stiffness or flexibility desired in the final product. The helical coil **17** is about 20 to about 45 cm in length, has an outer diameter about the same size as the diameter of the elongated proximal portion **11**, and is made from wire about 0.002 to 0.003 inch in diameter. The shaping ribbon **22** and the flattened distal section **26** of distal portion **12** have rectangular transverse cross-sections which usually have dimensions of about 0.001 by 0.003 inch.

The superelastic members of the invention, i.e. the distal portion **12** and the connector **13**, is preferably made of an alloy material consisting essentially of about 30 to about 52% titanium and the balance nickel and up to 10% of one or more other alloying elements. The other alloying elements may be selected from the group consisting of iron, cobalt, vanadium, platinum, palla-

dium and copper. The alloy can contain up to about 10% copper and vanadium and up to 3% of the other alloying elements. The addition of nickel above the equiatomic amounts with titanium and the other identified alloying elements increase the stress levels at which the stress-induced austenite-to-martensite transformation occurs and ensure that the temperature at which the martensite phase transforms to the austenite phase is well below human body temperature so that austenite is the only stable phase at body temperature. The excess nickel and additional alloying elements also help to provide an expanded strain range at very high stresses when the stress induced transformation of the austenite phase to the martensite phase occurs.

A presently preferred method for making the final configuration of the superelastic portions of the guiding member is to cold work, preferably by drawing, a rod or tubular member having a composition according to the relative proportions described above and then heat treating the cold worked product while it is under stress to impart a shape memory thereto. Typical initial transverse dimensions of the rod or the tubular member are about 0.045 inch and about 0.25 inch respectively. If the final product is to be tubular, a small diameter ingot, e.g. 0.25 to about 1.5 inch in diameter and 5 to about 30 inches in length, may be formed into a hollow tube by extruding or by machining a longitudinal center hole therethrough and grinding the outer surface thereof smooth. Before drawing the solid rod or tubular member, it is preferably annealed at a temperature of about 500° to about 750° C., typically about 650° C., for about 30 minutes in a protective atmosphere such as argon to relieve essentially all internal stresses. In this manner all of the specimens start the subsequent thermomechanical processing in essentially the same metallurgical condition so that products with consistent final properties are obtained. Such treatment also provides the requisite ductility for effective cold working.

The stressed relieved stock is cold worked by drawing to effect a reduction in the cross sectional area thereof of about 30 to about 70%. The metal is drawn through one or more dies of appropriate inner diameter with a reduction per pass of about 10 to 50%. Other forms of cold working can be employed such as swaging

Following cold work, the drawn wire or hollow tubular product is heat treated at a temperature between about 350° and about 600° C. for about 0.5 to about 60 minutes. Preferably, the drawn wire or hollow tubular product is simultaneously subjected to a longitudinal stress between about 5% and about 50%, preferably about 10% to about 30% of the tensile strength of the material (as measured at room temperature) in order to impart a straight "memory" to the metal and to ensure that any residual stresses therein are uniform. This memory imparting heat treatment also fixes the austenite-martensite transformation temperature for the cold worked metal. By developing a straight "memory" and maintaining uniform residual stresses in the superelastic material, there is little or no tendency for a guidewire made of this material to whip when it is torqued within a patient's blood vessel.

An alternate method for imparting a straight memory to the cold worked material includes mechanically straightening the wire or tube and then subjecting the straightened wire to a memory imparting heat treatment at a temperature of about 300° to about 450° C., preferably about 330° to about 400° C. The latter treatment provides substantially improved tensile properties, but it is not very effective on materials which have been cold worked above 55%, particularly above 60%. Materials produced in this manner exhibit stress-induced austenite to martensite phase transformation at very high levels of stress but the stress during the phase transformation is not nearly as constant as the previously discussed method. Conventional mechanical straightening means can be used such as subjecting the material to sufficient longitudinal stress to straighten it.

FIG. 2 illustrates an idealized stress-strain relationship of an alloy specimen having superelastic properties as would be exhibited upon tensile testing of the specimen. The line from point A to point B thereon represents the elastic deformation of the specimen. After point B the strain or deformation is no longer proportional to the applied stress and it is in the region between point B and point C that the stress-induced transformation of the austenite phase to the martensite phase begins to occur. There can be an intermediate phase developed, sometimes called the rhombohedral phase, depending upon the composition of the alloy. At point C the material enters a region of relatively constant stress with significant deformation or strain. It is in this region that the transformation from austenite to martensite occurs. At point D the transformation to the martensite phase due to the application of tensile stress to the specimen is substantially complete. Beyond point D the martensite phase begins to deform, elastically at first, but, beyond point E, the deformation is plastic or permanent.

When the stress applied to the superelastic metal is removed, the metal will recover to its original shape, provided that there was no permanent deformation to the martensite phase. At point F in the recovery process, the metal begins to transform from the stress-induced, unstable martensite phase back to the more stable austenite phase. In the region from point G to point H, which is also an essentially constant stress region, the phase transformation from martensite back to austenite is essentially complete. The line from point I to the starting point A represents the elastic recovery of the metal to its original shape.

Because of the extended strain range under stress-induced phase transformation which is characteristic of the superelastic material described herein, a guidewire having a distal portion made at least in substantial part of such material can be readily advanced through tortuous arterial passageways. When the distal end of the guidewire engages the wall of a body lumen such as a blood vessel, it will superelastically deform as the austenite transforms to martensite. Upon the disengagement of the distal end of the guidewire from the vessel wall, the stress is reduced or eliminated from within the superelastic portion of the guidewire and it recovers to its original shape, i.e. the shape "remembered" which is preferably straight. The straight "memory" in conjunction with little or no nonuniform residual longitudinal stresses within the guidewire prevent whipping of the guidewire when it is torqued from the proximal end thereof. Moreover, due to the very high level of stress needed to transform the austenite phase to the martensite phase, there is little chance for permanent deformation of the guidewire or the guiding member when it is advanced through a patient's artery.

The tubular connector formed of superelastic alloy material provides a smooth transition between the high strength proximal portion and the relatively short distal

section and retains a torque transmitting relationship between these two portions.

The present invention provides guidewires which have superelastic characteristics to facilitate the advancing thereof in a body lumen. The guiding members exhibit extensive, recoverable strain resulting from stress induced phase transformation of austenite to martensite at exceptionally high stress levels which greatly minimizes the risk of damage to arteries during the advancement therein.

The Nitinol hypotubing from which the connector is formed generally may have an outer diameter from about 0.006 inch to about 0.02 inch with wall thicknesses of about 0.001 to about 0.004 inch. A presently preferred superelastic hypotubing for the connecting member has an outer diameter of about 0.014 inch and a wall thickness of about 0.002 inch.

Superelastic NiTi alloys, such as those described herein, are very difficult to solder due to the formation of a tenacious, naturally occurring oxide coating which prevents the molten solder from wetting the surface of the alloy in a manner necessary to develop a sound, essentially oxide free, soldered joint. It has been found that by first treating the surface of the refractory superelastic alloy with molten alkali metal hydroxide, e.g. sodium, potassium, lithium or mixtures thereof to form a nascent alloy surface and then pretinning with a suitable solder such as a gold-tin solder without contacting air, that the superelastic piece can be readily soldered in a conventional manner. A presently preferred alkali metal hydroxide is a mixture of about 59% K and about 41% Na. The solder may contain from about 60 to about 85% gold and the balance tin, with the presently preferred solder containing about 80% gold and about 20% tin In a presently preferred procedure a multilayered bath is provided with an upper layer of molten alkali metal hydroxide and a lower layer of molten gold-tin solder. The part of the superelastic distal portion, which is to be soldered, is thrust into the multilayered bath through the upper surface of the molten alkali metal hydroxide which removes the oxide coating, leaving a nascent metal alloy surface, and then into the molten solder which wets the nascent metal surface. When the solder solidifies upon removal from the molten solder into a thin coating on the metal alloy surface, the underlying alloy surface is protected from an oxygen-containing atmosphere. Any of the alkali metal hydroxide on the surface of the solder can be easily removed with water without detrimentally affecting either the pretinned layer or the underlying alloy surface. The superelastic member is then ready for conventional soldering. The procedure may be employed to prepare other metal alloys having significant titanium levels for soldering.

The high strength proximal portion of the guidewire generally is significantly stronger, i.e. higher ultimate tensile strength, than the superelastic distal portion. Suitable high strength materials include **304** stainless steel which is a conventional material in guidewire construction.

While the above description of the invention is directed to presently preferred embodiments, various modifications and improvements can be made to the invention without departing therefrom.

What is claimed is:

1. An intravascular guidewire having proximal and distal ends, comprising:

a) an elongated high strength proximal portion having proximal and distal ends;

b) a distal portion having proximal and distal ends formed of a superelastic alloy in an austenite phase at body temperature, which transforms to a martensite phase when subjected to stress; and

c) means for connecting the distal end of the proximal portion and the proximal end of the distal portion, which is formed at least in part of a superelastic alloy in an austenite phase which transforms to a martensite phase when subjected to stress.

2. The guidewire of claim **1** wherein the means for connecting the distal end of the proximal portion to the proximal end of the distal portion has a tubular construction with an inner lumen extending therein, with a proximal end receiving the distal end of the proximal portion and a distal end receiving the proximal end of the distal portion.

3. The guidewire of claim **2** wherein the connector means having a tubular construction has an outer diameter of about 0.006 to about 0.05 inch and a wall thickness of about 0.001 to about 0.004 inch.

4. The guidewire of claim **1** wherein a flexible coil is disposed about the distal portion and extends to a rounded plug in the distal end of the guidewire.

5. The guidewire of claim **1** wherein the distal portion terminates short of the distal end of the guidewire and a non-superelastic shaping ribbon extends from the distal section to the rounded plug.

6. The guidewire of claim **5** wherein the distal portion is formed of a superelastic alloy consisting essentially of about 40 to about 49% titanium and the balance nickel and up to 10% of other alloying elements.

7. The guidewire of claim **6** wherein the other alloying elements are selected from the group consisting of iron, cobalt, vanadium and copper.

8. The guidewire of claim **7** wherein the alloy contains vanadium or copper in amounts up to about 10% and the other alloying elements up to about 3%.

9. The guidewire of claim **1** wherein the superelastic distal portion has a straight memory.

10. The guidewire of claim **1** wherein the strain of the distal portion during the transformation from the austenite phase to the martensite phase is within the range of about 2% to about 8%.

11. The guidewire of claim **10** wherein the austenite-to-martensite transformation occurs at a relatively constant yield stress above about 50 ksi.

12. The guidewire of claim **10** wherein the austenite-to-martensite transformation occurs at a relatively constant yield stress above about 70 ksi.

13. The guidewire of claim **10** wherein the austenite-to-martensite transformation occurs at a relatively constant yield stress above about 90 ksi.

14. The guidewire of claim **1** wherein the distal portion has a section which tapers in the distal direction.

15. The guidewire of claim **1** wherein a lubricous polymer coating covers at least part of the proximal portion.

16. The guidewire of claim **1** wherein the superelastic distal portion exhibits a strain of at least 5% during the stress induced transformation from the austenite phase to the martensite phase.

17. An intravascular guidewire having proximal and distal ends, comprising:

a) an elongated high strength proximal portion having proximal and distal ends;

b) a distal portion having proximal and distal ends formed of a superelastic alloy in a stable austenite phase at body temperature, which transforms to a martensite phase when subjected to stress; and

c) a connecting member fixed to the distal end of the proximal portion and to the proximal end of the distal portion to effect a torque transmitting relationship therebetween.

18. The guidewire of claim **17** wherein a flexible coil is disposed about the distal portion and extends to a rounded plug in the distal end of the guidewire.

19. The guidewire of claim **17** wherein the superelastic distal portion has a straight memory.

20. The guidewire of claim **17** wherein the strain of the distal portion during the transformation from the austenite phase to the martensite phase is within the range of about 2% to about 8%.

21. The guidewire of claim **20** wherein the austenite-to-martensite transformation occurs at a relatively constant yield stress above about 50 ksi.

22. The guidewire of claim **20** wherein the austenite-to-martensite transformation occurs at a relatively constant yield stress above about 70 ksi.

23. The guidewire of claim **17** wherein the connector is a tubular member with an inner lumen extending therein which is configured to receive the proximal end of the distal portion and the distal end of the proximal portion.

24. The guidewire of claim **23** wherein the connector has an outer diameter of about 0.006 to about 0.05 inch and a wall thickness of about 0.001 to about 0.004 inch.

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